

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/182,62	1 01/13/94	ENGELHARDT	D	ENZ52
			REES, D	EXAMINER
		18N1/1031	107100	DADED WINGED
	APEUTICS, IN		ART UNIT	PAPER NUMBER
ENZO DIAG	NOSTICS, INC HEM, INC.	•		٦٠
575 FIFTH	AVENUE, 18T	H FLOOR .	1807	
NEW YORK,	NY 10017		DATE MAILED:	10/31/95
This is a communicat COMMISSIONER OF	tion from the examiner in PATENTS AND TRAD	charge of your application. EMARKS		
A shortened statutory	has been examined	Responsive to communication filed on 12 this action is set to expire month(s), nse will cause the application to become abandor	_ days	This action is made final. from the date of this letter.
		s) ARE PART OF THIS ACTION:		
1. Notice of	References Cited by Ex Art Cited by Applicant, F	aminer, PTO-892.		Patent Drawing Review, PTO-948. ent Application, PTO-152.
	OF ACTION			
Partii Sommani				
1. Claims	1-90			are pending in the application.
Of the	above, claims			are withdrawn from consideration.
2. Claims		· · · · · · · · · · · · · · · · · · ·		have been cancelled.
3. Claims				are allowed.
4. Claims				are rejected.
				are objected to.
6. Claims	1-90		are subject to restri	ction or election requirement.
7. This applica	ution has been filed with	informal drawings under 37 C.F.R. 1.85 which are	acceptable for ex	amination purposes.
•••		ponse to this Office action.		
9. The corrects are access	ed or substitute drawing: eptable; 🔲 not acceptab	s have been received on le (see explanation or Notice of Draftsman's Pate	nt Drawing Review	, PTO-948).
10. The propose examiner;	ed additional or substitu disapproved by the e	te sheet(s) of drawings, filed on xaminer (see explanation).	has (have) bee	n Dapproved by the
11. The propos	ed drawing correction, fil	ed, has been 🔲 appn	oved; disappro	ved (see explanation).
12. Acknowledg	gement is made of the ci d in parent application, s	alm for priority under 35 U.S.C. 119. The certifile serial no; filed on	d copy has Dee	n received not been received .
13. Since this a accordance	pplication apppears to be with the practice under	e in condition for allowance except for formal mat Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.	iters, prosecution a	s to the merits is closed in
14. Other				

EXAMINER'S ACTION

08182621

Serial Number: 08182621

Art Unit: 1807

Part III DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-51 and 73-80, drawn to an in vitro process for producing more than one copy of a nucleic acid, classified in Class 435, subclass 91.2.

Group II. Claims 52-72, drawn to a promoter-independent non-naturally occurring nucleic acid construct which when present in a cell produces a nucleic acid without the use of any gene product coded by said construct, and nucleic acid conjugates of this construct, classified in Class 435, subclass 320.1, for example.

Group III. Claims 81-90, drawn to a construct comprising a host promoter located on the construct such that the host transcribes a sequence in the construct coding for a different RNA polymerase, classified in Class 435, subclass 69.1 for example.

Art Unit: 1807

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II, and III vs Invention I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the process may be practiced without the constructs of inventions II and III, using simply RNA primers for example. Further the products of invention II and III may be used respectively in different processes. The product of invention II may be used in processes that involve the controllable regulation of gene expression for the overproduction of proteins, while the product of invention III may be used in a method of purification of RNA polymerases.

Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations. (M.P.E.P. § 806.05(c)). In the instant case, the combination as claimed does not require the

Serial Number: 08182621

Art Unit: 1807

particulars of the subcombination as claimed because the construct of invention I does not require a nucleic acid sequence encoding a polymerase. The subcombination has separate utility such as overexpressing RNA polymerase for the purpose of purifying this protein.

- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 4. A telephone call was made to Enzo Therapeutics on Oct 26, 1995 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition

Serial Number: 08182621

Art Unit: 1807

under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

6. Papers related to this application may be submitted to Group 1800 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center number is (703) 308-7939. Please note that the faxing of such papers must conform with the notice to Comply published in the Official Gazette, 1096 OG 30 (Nov 15, 1989).

An inquiry regarding this communication should be directed to examiner Dianne Rees, Ph.D., whose telephone number is (703) 308-6565. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1156.

Calls of a general nature may be directed to the Group receptionist who may be reached at (703) 308-0196.

Dianne Keas

Diamie Rees

Oct 27, 1995

W. GARY JONES
SUPERVISORY PATENT EXAMINER

GROUP 1800

10/30/95